

REMARKS

1. Amendment – Specification

In response to the Examiner's request and pursuant to 37 CFR 1.125(a), Applicant hereby substitutes the specification as originally filed with the substitute specification accompanying this response. As will be noted, the accompanying replacement specification has numbered paragraphs instead of line numbering. Applicant respectfully submits that the accompanying substitute specification, meets all of the requirements of 37 CFR 1.125(a), and does not contain new matter.

Amendments included in the substitute specification include those previously made to the title, abstract, and specification as originally filed, which amendments were made in Applicant's prior responses dated 30 July 2004 and 25 June 2001.

In the accompanying substitute specification, Applicant has endeavored to retain as closely as possible the pagination in the specification as originally filed. To assist the Examiner, Applicant has also included a redline version of the substitute specification so that the changes made to the original specification can be easily ascertained. Applicant notes that amendments have been made to the title, abstract and to paragraph 45 on page 12-13, paragraph 56 on page 17, paragraph 71 on page 22, paragraph 74 on page 22-23, paragraph 160 on page 40-41, paragraph 164 on page 42, paragraph 170 on page 43, paragraphs 174 and 179 on page 44, paragraph 193 on page 46, paragraph 195 on page 47, paragraph 210 on page 49, paragraph 487 on page 93, paragraph 489 on page 94, paragraph 539 on page 104, paragraph 550 on page 106, and paragraph 551 on page 106. Applicant has also corrected spelling errors, such as that noted in paragraph 256 on page 57.

2. Objections to Specification

The Examiner, citing 37 CFR 1.75 (d) (1) and MPEP Section 608.01 (o), has objected to the specification for failing to provide proper antecedent basis for the subject matter as now claimed for allegedly lacking an antecedent basis for the claimed methods of identifying a T cell specific for an antigen of interest, as in claim 383, or for methods wherein a label is bound to cholesterol, as in claim 390. Applicant respectfully traverses, and directs the Examiner's

attention to, for example, paragraph 38 on page 10 of the accompanying substitute specification. There, the specification expressly provides that Applicant's artificial antigen presenting cell platform technology "is versatile and applicable to all situations where the isolation, identification, and modulation of T cells is of clinical import." (emphasis added) Paragraph 125 on page 31 states, "The *ex vivo* application of the current invention is preferred because specific peptides can be used to isolate and identify antigen-specific T cells ...". Applicant respectfully states that these passages, as well as others in the specification, provide the requisite antecedent basis for the claimed methods directed to identifying antigen-specific T cells.

With respect to cholesterol-bound labels, Applicant directs the Examiner's attention first to paragraph 72 on page 22, which states that the "Phospholipids contemplated include neutrally charged phospholipids such as phosphatidylcholine and cholesterol." (emphasis added). Paragraphs 74 and 174 go on to teach that the label can be associated with components of the liposome, including the lipids that comprise a lipid bilayer. *See* also Figure 4. Accordingly, Applicant maintains that the specification provides the requisite antecedent basis for claim 390.

3. New Ground of Rejection

Claims 383-391 stand rejected under 35 U.S.C. § 112, first paragraph, because the specification allegedly lacks a written description for artificial antigen presenting cells (aAPCs) wherein the peptide presented on the aAPCs is derived from an antigen of interest. Applicant respectfully traverses.

The written description requirement of 35 U.S.C. § 112, first paragraph, is satisfied when a patent application teaches those ordinarily skilled in the art that the patent applicant possessed the invention as of the application's priority date. Moreover, it is not necessary that exact words used in the claim be found in the specification – this question is whether those of ordinary skill in the art would understand that the applicant possessed the invention as claimed. Contrary to the suggestion in the Office action that support for the inclusion in aAPC of a peptide derived from an antigen of interest, the specification is replete with such support, and thus those skilled in the art would certainly appreciate that the claimed methods would involve the use of aAPCs that contain peptides derived from an antigen of interest.

In support of this position, the Examiner's attention is respectfully directed to paragraph 73 on page 22. There, the specification states:

“In still another embodiment, the APC comprises antigens wherein the antigens are presented by an MHC components for contact with and recognition by a T cell receptor. Such antigens may be selected from the group consisting of a peptide, a peptide derived from the recipient for graft versus host disease, a cancer cell-derived peptide, a peptide derived from an allergen, a donor-derived peptide, a pathogen-derived molecule, a peptide derived by epitope mapping, a self-derived molecule, a self-derived molecule that has sequence identity with said pathogen-derived **antigen**, said sequence identity having a range selected from the group consisting of between 5 and 100%, 15 and 300%, 35 and 100%, and 50 and 100%.” (emphasis added)


As clearly indicated by the above paragraph alone, one of skill in the art will understand that the peptide of claim 383 is one derived from an antigen of interest. Accordingly, the instant rejection should be withdrawn.

4. Conclusion

Applicant respectfully submits the instant application satisfies all requirements for patentability and that the pending claims are in condition for allowance. An early notice to such effect would be appreciated. Should any issues or questions remain, the Examiner is encouraged to telephone the undersigned at 858.350.9690 so that they may be promptly resolved.

Respectfully submitted,

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